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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/821,694   | 04/09/2004  | Christa Harris       | THR-6198UTIL        | 1151             |
| 7590   | 11/16/2005  |                      | EXAMINER            |                  |
| ALLEGIANCE CORPORATION   |             |                      | ROANE, AARON F      |                  |
| Attn: Kim Luna, KB-1A<br>1430 Waukegan Rd<br>McGaw Park, IL 60085-6787 |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 3739                |                  |

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                 |                 |
|------------------------------|-----------------|-----------------|
| <b>Office Action Summary</b> | Application No. | Applicant(s)    |
|                              | 10/821,694      | HARRIS, CHRISTA |
|                              | Examiner        | Art Unit        |
|                              | Aaron Roane     | 3739            |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 21 September 2005.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1 and 3-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1 and 3-15 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9/21/2005.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5-8 and 11-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Silver (USPN 5,897,580).

Regarding claim 1, Silver discloses a warming device (10) comprising: an exothermic thermochemical composition (26) wherein the exothermic reaction occurs upon activation; a flexible polymeric containment (10 composed of layers 12 and 14) for said thermochemical composition, said containment being structured to have a first skin-contacting side (12) and second transparent viewing side (14), each of said first and second sides having an interior surface and exterior surface; wherein said first skin-contacting side of said containment further comprises an outer fabric layer (30) attached onto said skin-contacting side surface, see col. 1-6, particularly col. 2, line 10 through col. 5, line 23 and figures 1-7.

Regarding claim 3, Silver further discloses said second viewing side is composed of a transparent polymeric material permitting viewing of the interior of said flexible polymeric containment, see col. 3, lines 6-19.

Regarding claims 5 and 6, Silver further discloses the claimed invention, see col. 4, lines 38-56 and figure 7. Additionally, it should be noted the recitation of the outer fabric layer adhered onto said first skin-contacting side by an adhesive, is interpreted as a method of manufacture. The determination of patentability in a product-by-process claim is based on the product itself, even though the claim may be limited and defined by the process. That is, the product in such a claim is unpatentable if it is the same as or obvious from the product of the prior art, even if the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985). A product-by-process limitation adds no patentable distinction to the claim, and is unpatentable if the claimed product is the same as a product of the prior art.

Regarding claims 7 and 8, Silver further discloses said outer fabric layer is composed of a non-woven material made from rayon, see col. 4, lines 38-46.

Regarding claims 11-15, Silver further discloses the claimed invention. In col. 4, lines 23-32, Silver incorporates by reference Stanley et al. (USPN 4,077,390), Fiedler (USPN 4,572,158) and Manker (USPN's 4,872,442, 4,880,953 and 5,058,563). Manker (USPN 4,872,442) discloses the claimed invention, see entire reference.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheney, III (USPN 5,143,048) in view of Silver (USPN 5,897,580) in further view of Manker (USPN 5,800,492).

Regarding claims 1 and 4, Cheney, III discloses an infant heel warming device (10) comprising: an exothermic thermochemical composition (15) wherein the exothermic reaction occurs upon activation, see col. 1-4 and figures 1-4. Cheney, III fails to disclose a flexible polymeric containment for said thermochemical composition, said containment being structured to have a first skin-contacting side and second transparent viewing side, each of said first and second sides having an interior surface and exterior surface; wherein said first skin-contacting side of said containment further comprises an outer fabric layer attached onto said skin-contacting side surface. Cheney, III also fails to disclose at least one securing strap is attached to said device to secure said device onto

the foot. Silver discloses a warming device (10) comprising: an exothermic thermochemical composition (26) wherein the exothermic reaction occurs upon activation; a flexible polymeric containment (10 composed of layers 12 and 14) for said thermochemical composition. Silver teaches providing a containment being structured to have a first skin-contacting side (12) and second transparent viewing side (14), each of said first and second sides having an interior surface and exterior surface in order to locate the triggering element. Additionally, Silver teaches providing said first skin-contacting side of said containment with an outer fabric layer (30) attached onto said skin-contacting side surface in order to provide extra comfort to the user, see col. 1-6, particularly col. 2, line 10 through col. 5, line 23 and figures 1-7. Manker discloses an adhesive warming bag (10) and teaches providing the bag (10) with at least one strap (14) in order to properly secure the bag to an infant's foot, see col. 3 and figures 1-6. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Cheney, III, as taught by Silver, to provide a flexible containment being structured to have a first skin-contacting side and second transparent viewing side in order to contain the heating composition and in order to locate the triggering element, and as also taught by Silver, to provide the first skin-contacting side of said containment with an outer fabric layer attached onto said skin-contacting side surface in order to provide extra comfort to the user, and as finally taught by Manker, to providing the device with at least one strap in order to properly secure the bag to an infants foot.

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silver (USPN 5,897,580) in view of Angelillo et al. (USPN 5,736,110).

Regarding claim 9, Silver discloses the claimed invention except for reciting the thermochemical composition comprises a liquid mixture of sodium acetate trihydrate and water. Silver does state “the chemical composition 26 may be any chemical or mixture of chemicals that undergoes an exothermic reaction. Preferably the exothermic reaction is reversible,” see col. 4, lines 12-22. It is extremely well known in the art that sodium acetate trihydrate is used in thermal devices wherein the application of thermal energy is triggered by a physical activator. Angelillo et al. disclose a thermal device that is triggered and teach the use of super saturated sodium acetate trihydrate in order to provide reusable heating, see col. 6-11. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Silver, as is known in the art and taught by Angelillo et al., to use super saturated sodium acetate trihydrate in order to provide reusable heating.

Regarding claim 10, Silver in view of Angelillo et al. disclose the claimed invention. Silver in view of Angelillo et al. is silent as to the ratio of sodium acetate trihydrate to water other than the sodium acetate trihydrate is super saturated (large amount of sodium acetate trihydrate to small amount of water). At the time of the invention, it would have been an obvious matter of design choice to one of ordinary skill in the art to use a mixture of sodium acetate trihydrate present in an amount of about 73% of the total liquid volume

and water present in an amount of about 27% of the total liquid volume because Applicant has not disclosed this particular ratio provides an advantage, is used for a particular purpose, or solves a stated problem compared to a simple super saturated solution of sodium acetate trihydrate and water. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with a simple super saturated solution of sodium acetate trihydrate and water or a mixture of sodium acetate trihydrate present in an amount of about 73% of the total liquid volume and water present in an amount of about 27% of the total liquid volume because they both provide the necessary reusable heat source though the physical activation of the trigger.

***Response to Arguments***

Applicant's arguments filed 9/21/2005 have been fully considered but they are not persuasive. The examiner will address each argument/remark in turn.

In response to applicant's argument that Silver does not disclose an infant heel warming device, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

There are no structural and/or functional features claimed that distinguish the presently claimed invention, as set forth by the language of claim 1 that distinguish over the Silver patent. The amendment to claim 1 is simply a change from "a warming device" to "an infant heel

warming device", which although it may breathe life into the claim does not preclude a broader interpretation than Applicant intends and/or the use of Silver alone for a rejection.

Regarding Applicant's refutation of the rejections based on Cheney, III and Silver, and states "one of ordinary skill in the art would not have viewed Silver and combined its teachings with Cheney, III." In response to applicant's argument that Cheney, III and Silver are nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Both Cheney, III and Silver are thermal devices that provide exothermic reactions by activating a metallic trigger.

Additionally, The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. *In re Keller*, 642 F. 2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). In this regard, a conclusion of obviousness may be based on common knowledge and common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference. *In re Bozek*, 416 F.2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969). Additionally, the examiner directs Applicant to col. 3, lines 12-19 of Silver, which supports the examiner's determination that one of ordinary skill in the art at the time of the invention would have a motivation for combining the references.

Regarding the Manker reference used in the rejection of claims 1 and 4, the examiner inadvertently used the wrong patent number. The previous office action reported that the Manker U.S. Patent number as 4,872,442. However that was a typographical error on the part of the examiner. USPN 4,872,442 is not the correct patent number. Presently, the examiner has provided the appropriate Manker patent number, it is USPN 5,800,492. The examiner directs Applicant to Manker USPN 5,800,492 and the noted passage above.

Regarding the remainder of Applicant's arguments/remarks, the examiner directs Applicant to the above rebuttals.

As noted above, the previous Office Action inadvertently presented the wrong Manker U.S. Patent number (USPN 4,872,442) instead of the correct Manker U.S. Patent number (USPN 5,800,492), therefore **this action is NON-FINAL**, in order to give Applicant an opportunity to respond to the Office's search, examination and presentation of prior art in all fairness.

***Again, this action is NON-FINAL.***

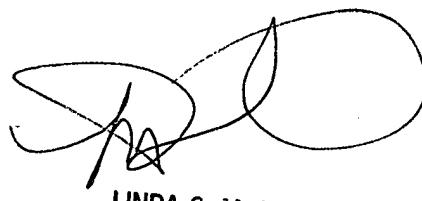
### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (571) 272-4771. The examiner can normally be reached on Monday-Thursday 7AM-6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.R. *A.R.*  
October 17, 2005



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